UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

In re INTUNIV ANTITRUST LITIGATION This Document Relates to: *Direct Purchaser Actions*	Civil Action No. 1:16-cv-12653-ADB **REDACTED PUBLIC VERSION**

DEFENDANTS' OPPOSITION TO DIRECT PURCHASER CLASS PLAINTIFFS' MOTION FOR CLASS CERTIFICATION

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Defendants Shire LLC, Shire US, Inc., Actavis Elizabeth LLC, and Actavis Holdco U.S., Inc. (collectively, "Defendants") oppose the direct purchaser class plaintiffs' ("DPPs") motion for class certification (ECF No. 198).[1]

INTRODUCTION

Rule 23 "imposes stringent requirements for certification that in practice exclude most claims."[2] The DPPs nevertheless insist that courts frequently certify direct-purchaser classes in pharmaceutical antitrust cases, and they argue that their challenge to the patent license agreement for the drug Intuniv entered between Shire and Actavis "is no different."[3] In fact, however, courts have increasingly questioned whether antitrust actions brought by direct purchasers of drug products should proceed as class actions, with multiple recent decisions denying class certification.[4] And in any event, this case presents several unique circumstances that plainly make class certification inappropriate.

Class actions seeking damages under Rule 23(b)(3) are intended to facilitate recovery when the defendants' alleged conduct "inflicts small amounts of damage on large numbers of people" in a common way that can be proved using common evidence.[5] This case is the exact opposite of that paradigm. The DPPs seek hundreds of millions of dollars in damages on behalf of a class that, even based on the DPPs' own improperly inflated count, includes fewer than 50 members who purchased Intuniv or its generic equivalent. Most remarkably, [redacted]

[redacted]

[1] On February 4, 2019, the Court granted Defendants' motion to seal and their motion for leave to file excess pages in connection with their oppositions to the Motions for Class Certification by the Direct Purchaser and Indirect Purchaser Plaintiffs. ECF Nos. 158 and 159 (16-cv-12396-ADB).

[2] *Am. Exp. Co. v. Italian Colors Rest.*, 570 U.S. 228, 234 (2013).

[3] Mem. of Law in Supp. Of Direct Purchaser Class Pls.' Mot. for Class Certification ("DPP Mem.") 1 & n.3, 9 (associated with ECF No. 198).

[4] *See* notes 152-153 and accompanying text, *infra*.

[5] *In re Asacol Antitrust Litig.*, 907 F.3d 42, 56 (1st Cir. 2018).

[redacted].[6] Yet those entities—the so-called "Big Three" wholesale purchasers—are somehow *not* among the class representatives.

Instead, the case is being led by two fundamentally atypical and inadequate named plaintiffs. The first named representative, FWK Holdings, LLC ("FWK"), is a litigation-only entity that plays no role in the pharmaceutical industry and was formed (and funded) by several of the class counsel and one of their business associates to purchase antitrust claims and bring them as class actions. No court has approved FWK as a class representative, and this Court should not be the first: FWK's [redacted] make it impossible to believe that FWK will serve as a genuine "fiduciar[y]" for absent class members by "monitoring the lawyers who prosecute the case."[7] The second named representative, Rochester Drug Co-Operative ("RDC"), [redacted] makes it a fundamentally inappropriate class representative.

Even apart from the inadequacy and atypicality of the named class representatives, the proposed class cannot be certified. The proposed class does not satisfy Rule 23(a)(1)'s "numerosity" requirement because joinder of the plaintiffs is entirely practicable. To avoid that conclusion, the DPPs artificially try to increase the size of the proposed class by, for example, double-counting corporate affiliates and grouping fundamentally different types of purchasers together without using subclasses. The Court should reject the DPPs' attempted inflation of the

[6] Declaration of Gregory K. Bell, Ph.D. ("Bell Report") ¶ 49, attached hereto as Exhibit 1 to the Declaration of Alicia Rubio-Spring, Esq. Unless otherwise specified, all citations to exhibits in this Memorandum refer to exhibits attached to the Rubio-Spring Declaration.

[7] *Redman v. RadioShack Corp.*, 768 F.3d 622, 638 (7th Cir. 2014) (quotation marks and citation omitted).

class size, which in any event cannot obscure the fact that absent class members—including the Big Three—have ample incentive and ability to participate in this case as joined parties.

Finally, and in addition, the DPPs fail to show that common issues predominate over individual ones, as required under Rule 23(b)(3), because they do not provide a viable method for proving antitrust impact and damages on a classwide basis. The expert report that they rely on suffers from several shortcomings, including [redacted].

For these reasons, and as set forth further below, the Court should deny the DPPs' motion for class certification.[8]

BACKGROUND FACTS

In the course of briefing ostensibly devoted to their class certification motions, the Plaintiffs spend several pages trying to advance their claims on the merits.[9] Their presentation is simply inconsistent with the facts of this case, as they have emerged during the course of discovery.

A. The Launch And Marketing Of Intuniv.

Intuniv is an extended release formulation of guanfacine, a non-stimulant drug prescribed to treat ADHD. FDA approved Intuniv on September 2, 2009, and Shire began marketing the drug shortly thereafter.[10] [redacted]

[8] At a minimum, the Court should reject the DPPs' proposed starting point for the class period, which illogically commences ***before*** the challenged settlement was even entered. The broadest possible class period would begin no earlier than April 25, 2013, which is the date on which Defendants allegedly entered into an anticompetitive agreement. Defs.' Mem. in Opposition to Indirect Purchaser Class Pls.' Mot. for Class Certification ("IPP Opp.") at 43-45.

[9] *See* DPP Mem. 3-9; Mem. in Supp. Of Indirect Purchaser Pls.' Mot. for Class Certification ("IPP Mem.") 2-10, ECF No. 148, 16-cv-12396.

[10] NDA Approval Letter from Thomas Laughren, M.D., U.S. Food & Drug Admin., to Shire Pharmaceuticals, Inc. (Sept. 2, 2009), *available at* https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2009/022037s000ltr.pdf.

[redacted].[11]

Shire marketed Intuniv as an alternative monotherapy and an adjunctive therapy to stimulant ADHD treatments.[12] [redacted].[13] [redacted].[14] Shire offered the coupon program from 2011 to 2015. [redacted].[15]

[redacted].[16]

B. Shire's Intuniv Patent Infringement Litigations.

Shire held rights under three "Orange Book" patents that covered Intuniv: U.S. Patent Nos. 5,854,290 ("the '290 patent"), 6,287,599 ("the '599 patent"), and 6,811,794 ("the '794

[11] *See* Ex. 2 (SHIREINT0214658, at 11, 58-59).
[12] U.S. Food & Drug Admin., *Label for NDA 022037*, at 1 (2018), *available at* https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/022037s009lbl.pdf. Shire initially marketed Intuniv only as an alternative monotherapy until FDA approved Intuniv's adjunctive indication in 2011. *Id*. Under an adjunctive treatment regimen, patients take Intuniv in the evening—because, as a non-stimulant, it is less likely to interfere with sleep—and take a stimulant ADHD drug during the day.
[13] Ex. 3 (SHIREINT0228976, at 4-5, 18).
[14] *See, e.g.*, *id*.
[15] Ex. 4 (SHIREINT0215600, at 13-22); Ex. 5 (SHIREINT0274284).
[16] Ex. 3 (SHIREINT0228976, at 10).

patent").[17] The '599 and '794 patents expire on December 20, 2020 and July 4, 2022, respectively, and each has an additional six months of pediatric exclusivity attached.[18] The '290 patent was originally scheduled to expire on September 21, 2015, but Shire's licensor dedicated it to the public on March 22, 2012.[19]

In December 2009, Old Actavis[20] filed an abbreviated new drug application ("ANDA") with FDA to manufacture and sell a generic version of Intuniv. Old Actavis received "first to file" status for its ANDA, which included certifications that all three of Shire's Intuniv patents were invalid, unenforceable and/or not infringed ("Paragraph IV" certifications).[21] In January 2010, Anchen Pharmaceuticals, Inc. ("Anchen")[22] and Teva Pharmaceuticals, Inc. ("Teva") filed ANDAs to make and sell generic Intuniv.[23] Both ANDAs included Paragraph IV certifications.[24]

[17] *See generally* U.S. Patent No. 5,854,290 (filed Sept. 21, 1995), *available at* https://bit.ly/2Sxbmix (last visited Feb. 4, 2019); U.S. Patent No. 6,287,599 (filed Dec. 20, 2000), *available at* https://bit.ly/2HNIePx (last visited Feb. 4, 2019); U.S. Patent No. 6,811,794 (filed Dec. 20, 2001), *available at* https://bit.ly/2tdgSIR (last visited Feb. 4, 2019).

[18] U.S. Food & Drug Admin., *Patent and Exclusivity for: N022037*, Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations, *available at* https://bit.ly/2HTBgca (last visited Feb. 1, 2019).

[19] '290 Patent, Disclaimer and Dedication, *available at* https://bit.ly/2Sxbmix (last visited Feb. 4, 2019).

[20] "Old Actavis" refers to the company that filed ANDA No. 20-0881, the first-filer ANDA. *See* Letter from Gregory P. Geba, M.D., M.P.H., U.S. Food & Drug Admin., to Actavis Elizabeth LLC (Oct. 5, 2012), *available at* https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2012/200881Orig1s000ltr.pdf. In April 2012, Old Actavis entered into an agreement to sell many of its assets to Watson Pharmaceuticals, Inc. ("Watson"). That transaction was completed on October 31, 2012. A few months later, Watson changed its name to "Actavis." For purposes of this Memorandum, "Old Actavis" refers to the legacy company and "Actavis" refers to the affiliates of the renamed Watson company that are defendants in this antitrust case.

[21] *Id*.

[22] TWi Pharmaceuticals, Inc. ("TWi") owned the ANDA that was submitted to FDA by Anchen, TWi's registered agent. Together, the companies are referred to as TWi/Anchen.

[23] *See* ANDA Approval Letter from Carol A. Holquist, RPh, U.S. Food & Drug Admin., to Par Pharmaceutical, Inc. (June 2, 2015), *available at* https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2015/201408Orig1s000ltr.pdf (noting TWi/Anchen's ANDA submitted Jan. 28, 2010); ANDA Approval Letter from Carol A. Holquist, RPh, Food & Drug Admin., to Teva Pharmaceuticals USA (June 2, 2015), *available at* https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2015/201382Orig1s000ltr.pdf (noting Teva's ANDA submitted Jan. 25, 2010).

[24] *Id*.

Shire filed patent infringement lawsuits against each of these companies in the United States District Court for the District of Delaware.[25] On August 2, 2010, the court consolidated the three cases (the "Intuniv Patent Litigation").[26] Shire's filings triggered automatic 30-month stays preventing FDA from granting final approval to any generic applicant's ANDA, including a stay on approval of Old Actavis's ANDA until early October 2012. Subsequently, other generic companies, including Sandoz, filed ANDAs for generic versions of Intuniv and gave Shire notice of their Paragraph IV certifications.[27] Shire filed patent infringement lawsuits against each of these companies in different courts.

On March 22, 2012, the Delaware District Court issued a "Markman ruling" in the Intuniv Patent Litigation resolving disputes on the proper construction of certain patent terms, and in doing so adopted almost all of Shire's proposed claim construction terms.[28] One exception was that the court rejected both parties' proposed constructions for the term "pH dependent agent that increases the rate of release of said one pharmaceutically active agent from the tablet at a pH in excess of 5.5." Instead, the court fashioned its own construction that hewed more closely to Old Actavis's proposal.[29]

Eight months later, in Shire's case against Sandoz in the District of Colorado, that court construed the identical term differently, and adopted Shire's proposed claim construction instead—the same construction Shire had proposed in its litigation with Old Actavis.[30] Thus,

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[25] *Shire LLC v. Teva Pharm. USA, Inc.*, No. 10-cv-329, ECF No. 1, (D. Del. Apr. 22, 2010); *Shire LLC v. Actavis Elizabeth, LLC*, No. 10-cv-397, ECF No. 1 (D. Del. May 12, 2010); *Shire LLC v. Anchen Pharm., Inc.*, No. 10-cv-484, ECF No. 1 (D. Del. June 2, 2010).

[26] *See Shire LLC v. Teva Pharm. USA, Inc.*, No. 10-cv-329 ("Intuniv Patent Litigation"), ECF No. 15 (D. Del. Aug. 2, 2010).

[27] *See Shire LLC v. Impax Labs., Inc.*, No. 10-cv-5467, ECF No. 1 (N.D. Cal. Dec. 2, 2010); *Shire LLC v. Sandoz Inc.*, No. 11-cv-1110, ECF No. 1 (D. Colo. Apr. 27, 2011); *Shire LLC v. Mylan Pharm. Inc.*, No. 11-cv-55, ECF No. 3 (N.D. W. Va. Dec. 15, 2011).

[28] *Shire LLC v. Teva Pharm. USA Inc.*, 2012 WL 975694 (D. Del. Mar. 22, 2012).

[29] *Id.* at *5-7 & n.1.

[30] *See Shire LLC v. Sandoz Inc.*, 2012 WL 5494944, at *4 (D. Colo. Nov. 13, 2012).

even if Old Actavis (and other generic defendants) had prevailed in the Delaware District Court under Judge Andrews's claim construction, on appeal, the Federal Circuit would have been tasked with resolving whether Judge Andrews's construction was correct in view of the decision in Colorado, regardless of whether Sandoz had settled. This created a significant risk that any potential win by Old Actavis in the Delaware District Court would have been vacated on appeal.

On September 4, 2012, Shire entered a settlement agreement with TWi/Anchen before the Delaware District Court ruled on Anchen's summary judgment motion.[31] That agreement provided TWi/Anchen with a license to launch its generic Intuniv product on July 1, 2016 (or earlier under certain circumstances) and provided that TWi/Anchen would pay a royalty to Shire for its sales.[32] The agreement further provided that if Shire—in its sole discretion—chose to launch an Intuniv AG [redacted][33] [redacted], Shire would do so using supply from TWi/Anchen.[34]

Old Actavis moved for summary judgment of noninfringement (Teva did not file a motion), and Shire defeated that motion.[35] Shire's lawsuits against Old Actavis and Teva were then tried in the Delaware District Court from September 17 to September 20, 2012, with the court reserving decision.[36] Following trial, market analysts concluded that the bench trial was a close call, with some favoring Shire and others favoring Old Actavis. At least one analyst [redacted][37]

[31] Ex. 6 (SHIREINT0000001).
[32] *Id.* at -017, -023 ([redacted]), -034 ([redacted]).
[33] An "at-risk" launch refers to a launch by a generic company prior to a final non-appealable judgment in its favor on the merits of the patent litigation.
[34] Ex. 6 (SHIREINT0000001, at -027).
[35] Intuniv Patent Litigation, ECF Nos. 290, 291, 299, 325, 392-394, 440-443.
[36] Intuniv Patent Litigation, ECF Nos. 463-466.
[37] Ex. 7 (Actavis-Int-0081833, at -834).

C. Shire Prepares For An At-Risk Launch By Actavis.

FDA gave final approval to Old Actavis's generic Intuniv product on October 5, 2012.[38] As a regulatory matter, that approval allowed Old Actavis to launch "at-risk" if it chose to enter the market, despite the possibility that it could face many millions of dollars in infringement liability if Shire ultimately prevailed in the litigation.[39] [redacted][40] [redacted].[41]

In hindsight, none of those preparations was necessary. Old Actavis could not have launched at-risk without prior approval of Actavis, under the terms of the asset purchase agreement.[42] [redacted].[43]

At-risk launches in the generic industry are very rare. Actavis understood the tactic to present a number of substantial risks, including that the generic could be found liable and owe patent damages to the brand far exceeding its profits.[44] By contrast, launching only after a non-

[38] Letter from Gregory P. Geba, M.D., M.P.H., U.S. Food & Drug Admin., to Actavis Elizabeth LLC (Oct. 5, 2012), *available at* https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2012/200881Orig1s000ltr.pdf.
[39] *See, e.g.*, Ex. 8 (Bisaro Tr. 39:10-17, 42:3-24).
[40] *See* Ex. 9 (SHIREINT0226364-365); Ex. 10 (Badali Tr. 40:9-42:21, 112:6-113:25).
[41] *See, e.g.,* Ex. 11 (Miller Tr. 110:9-114:11); Ex. 12 (SHIREINT0221678).
[42] *See* Ex. 13 (Buchen Tr. 70:8-11, 83:13-17); Ex. 14 (Boothe Tr. 255:2-6).
[43] *See id*.
[44] *See* Ex. 8 (Bisaro Tr. 42:3-24); Ex. 13 (Buchen Tr. 71:24-75:22). At the time of the events in this case, Actavis had recently been forced to pay "tens of millions" of dollars as the consequence of an at-risk launch in which, even though the launch (by a predecessor company Actavis had acquired) had not occurred until after winning at the

appealable judgment, or based on a settlement, eliminates that risk and preserves the value of the 180-day regulatory exclusivity for a first-filer like Actavis. Actavis has undertaken very few at-risk launches.[45] Actavis management favored settling litigation and obtaining a licensed entry to avoid the "inherent uncertainty of litigation" and ensure that it obtained value from its ANDA.[46]

There is no evidence that Actavis obtained, or even requested, the requisite board approval for an at-risk launch of generic Intuniv. [redacted].[47] [redacted].[48] [redacted].[49] [redacted].[50]

District Court level, the decision had been reversed by the Federal Circuit and Actavis had been found liable for willful infringement on remand. Ex. 13 (Buchen Tr. 74:15-75:22).

[45] *See* Ex. 8 (Bisaro Tr. 36:11-14); Ex. 13 (Buchen Tr.70:12-19); Ex. 15 (Actavis Defs.' Supplemental Resps. & Objections to Indirect-Purchaser Pls.' First Set of Interrogs. at Interrog. No. 8).

[46] Ex. 16 (Actavis Defs.' Amended Objections & Resps. to Direct-Purchaser Pls.' Second Set of Interrogs. at Interrog. No. 13); *see also* Ex. 8 (Bisaro Tr. 93:9-94:7).

[47] *See* Ex. 14 (Boothe Tr. 264:2-22); Ex. 13 (Buchen Tr. 70:6-11). [redacted] Watson acquired Actavis, which was signed in April of 2012. *See id.* Before that agreement was signed, the FDA had not approved the generic Intuniv ANDA. *See* note 37, *supra*.

[48] *See* Ex. 16 (Actavis Defs.' Amended Objections & Resps. to Direct-Purchaser Pls.' Second Set of Interrogs. at Interrog. No. 6).

[49] *See* Ex. 14 (Boothe Tr. 203:14-204:6); Ex. 17 (Wu Tr. 52:25-53:6).

[50] Ex. 16 (Actavis Defs.' Amended Objections & Resps. to Direct-Purchaser Pls.' Second Set of Interrogs. at Interrog. No. 6).

D. Shire And Actavis Negotiate A Settlement Of Their Patent Litigation.

[redacted][51] [redacted][53] [redacted][54] [redacted][55] [redacted][56] [redacted][57] [redacted][58]

[51] Ex. 18 (Actavis-Int-0080808, at -818 ([redacted]), -825-26 ([redacted])).
[52] *See, e.g.*, Ex. 19 (Actavis-Int-0094048).
[53] *See, e.g.*, Ex. 20 (SHIREINT0253110).
[54] Ms. May and Mr. Buchen had an initial telephone call on November 20, 2012, and from that date until execution of the final settlement documents on April 25, 2013, they had many telephone calls. *See, e.g.*, Ex. 21 (SHIREINT0198953).
[55] U.S. Food & Drug Admin., *Patent and Exclusivity for: N022037*, Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations, https://bit.ly/2HTBgca (last visited Feb. 1, 2019).
[56] Ex. 22 (SHIREINT0273268); Ex. 23 (SHIREINT0162986, at -3000).
[57] Ex. 24 (Actavis-Int-0000001, at -016, Section 1.6).
[58] *See* Ex. 25 (Affidavit of Angus Russell ¶ 9).

[redacted].[59]

[redacted].[60]

[redacted].[61]

[redacted].[62]

[redacted].[63]

[59] [redacted] Ex. 16 (Actavis Defs.' Amended Objections & Resps. to Direct-Purchaser Pls.' Second Set of Interrogs. at Interrog. No. 13).

[60] Ex. 23 (SHIREINT0162986, at -3009 ([redacted])); Ex. 22 (SHIREINT0273268 ([redacted])).

[61] Ex. 26 (SHIREINT0155972 ([redacted])); Ex. 21 (SHIREINT0198953 ([redacted])).

[62] *See* Ex. 24 (Actavis-Int-0000001, at 026-27, Section 5.1.1).

[63] *See* Ex. 13 (Buchen Tr. 171:3-172:7).

[redacted].[64] [redacted]

[redacted].[65] [redacted]

[redacted][66]

[redacted][67] [redacted]

[redacted].[68] Shire's CEO, Angus Russell, [redacted]

[redacted].[69]

In the end, [redacted]

[redacted].[70] [redacted]

[64] *See id*. 158:15-21.
[65] Ex. 8 (Bisaro Tr. 64:21-65:24); *see Teva Pharm. USA, Inc. v. Sebelius*, 595 F.3d 1303, 1318 (D.C. Cir. 2010) (explaining that the 180-day exclusivity period is a "pro-consumer device" adopted by Congress to incentivize patent challenges by generic drug manufacturers and ultimately to facilitate generic competition).
[66] Ex. 27 (SHIREINT0197156); *see also* Ex. 13 (Buchen Tr. 158:15-159:2-4) (describing this dispute as "[redacted]").
[67] Ex. 23 (SHIREINT0162986, at -3007, Section 2.4).
[68] *See, e.g.,* Ex. 28 (SHIREINT0198472, at-495, Section 2.3).
[69] *See* Ex. 25 (Affidavit of Angus Russell ¶ 11).
[70] Ex. 24 (Actavis-Int-0000001, at -023, Section 2.3).

E. Shire's Considerations Of Whether To Launch An Intuniv AG In 2014, And Actavis's Recognition Of The Risk Of An AG Launch.

As the December 1, 2014 date of the Actavis launch approached, Shire [redacted].[71] [redacted].[72]

Shire's analysis revealed [redacted].[73] [redacted].[74] This analysis [redacted].[75] The [redacted], as the actual royalties that it received from Actavis [redacted]

[71] *See* Ex. 29 (SHIREINT0213350); Ex. 11 (Miller Tr. 160:13-162:7).
[72] An example of one of the many presentations evaluating Shire's options can be found at Exhibit 30 (SHIREINT0253534).
[73] While all of the issues that the IPPs claim are "impediments" that would dissuade Shire from launching an Intuniv AG were considered, none of them negatively impacted the analysis. *See, e.g.*, Ex. 30 (SHIREINT0253534) (showing consideration of Medicaid payments); Ex. 31 (SHIREINT0213635) (e-mail from Leonard Fasullo (Head of Supply for Intuniv) showing that [redacted]).
[74] A spreadsheet with a range of scenarios can be found at Exhibit 29 (SHIREINT0213350).
[75] *See* Ex. 30 (SHIREINT0253534).

[redacted].[76]

For its part, Actavis also fully understood that, even after the settlement agreement, Shire retained the right to launch an AG and might choose to do so. Actavis recognized that Shire had (or could develop) capacity to launch an AG itself or through an affiliate by its licensed entry date.[77] Actavis's internal forecasts for its sales team [redacted].[78] And in 2014, the head of sales instructed the sales team to gather competitive intelligence from the marketplace about a potential AG launch by Shire.[79]

Although Actavis ultimately heard nothing to suggest that an Intuniv AG was coming,[80] and thus planned accordingly, the very process of collecting the marketplace competitive intelligence belies any notion that Actavis somehow "knew" or "believed" that the settlement agreement precluded an Intuniv AG launch by Shire. Likewise, [redacted].

There is simply no evidence that Shire and Actavis agreed to a "no AG" provision of any kind.

ARGUMENT

"The class action is an exception to the usual rule that litigation is conducted by and on behalf of the individual named parties only."[81] As the movants, the DPPs "bear[] the burden of

[76] Ex. 32 (Shire's Resps. & Objections to Direct Purchaser Pls.' Second Set of Interrogs. at Interrog. No. 22); Ex. 30 (SHIREINT0253534, at 6).
[77] Ex. 13 (Buchen Tr. 180:15-181:3); Ex. 33 (Boyer Tr. 231:7-22); Ex. 34 (Actavis-Int-0121667).
[78] *See, e.g.*, Ex. 35 (Actavis-Int-0121841); Ex. 36 (Actavis-Int-0150763, at-764).
[79] Ex. 37 (Actavis-Int-0096026); *see also* Ex. 33 (Boyer Tr. 209:19-211:6); Ex. 38 (Meehan Tr. 188:15-190:19, 194:2-14).
[80] *See, e.g.*, Ex. 38 (Meehan Tr. 189:25-190:19, 194:2-14).
[81] *Wal-Mart Stores, Inc. v. Dukes*, 564 U.S. 338, 348 (2011).

establishing the elements necessary for class certification" under Rule 23.[82] Thus, the DPPs "must affirmatively demonstrate compliance with the Rule" by *proving* that they satisfy each element of Rule 23.[83] "The Rule 23(a) elements are (1) numerosity, (2) commonality, (3) typicality, and (4) adequacy of representation."[84] Because the DPPs seek to certify a Rule 23(b)(3) class, they also must show "that the questions of law or fact common to class members predominate over any questions affecting only individual members . . . , and that a class action is superior to other available methods for fairly and efficiently adjudicating the controversy."[85] "A failure to meet any one prong . . . is grounds for denying class certification."[86]

The DPPs' proposed class action fails to satisfy Rule 23 in several respects. Although the DPPs insist that it is "routine[]" for courts to certify direct-purchaser classes in antitrust cases,[87] they fail to grapple with the unique problems posed by their motion. [redacted].[88] Yet those three parties are absent from this litigation, which is instead being led by two representatives who are completely inadequate and atypical: (1) an artificial litigation entity (FWK) that was formed and funded by class counsel specifically so that they could bring class litigation; and (2) a company (RDC) that [redacted]. Far from routine, it would be remarkable to certify a class with these named representatives, while three entities who represent such a disproportionate share "of the

[82] *In re Relafen Antitrust Litig.*, 218 F.R.D. 337, 341 (D. Mass. 2003).
[83] *Dukes*, 564 U.S. at 350.
[84] *Smilow v. Sw. Bell Mobile Sys., Inc.*, 323 F.3d 32, 38 (1st Cir. 2003).
[85] *In re New Motor Vehicles Canadian Export Antitrust Litig.*, 522 F.3d 6, 18 (1st Cir. 2008).
[86] *Swanson v. Lord & Taylor LLC*, 278 F.R.D. 36, 39 (D. Mass. 2011) (quoting Fed. R. Civ. P. 23(a)).
[87] DPP Mem. 9 & n.55.
[88] Bell Report ¶ 49. [redacted]. *Id.* ¶ 89.

total value of class claims . . . sit on the sidelines."[89] For this reason, and for several others, the DPPs' certification motion should be denied.[90]

I. The Two Proposed Class Representatives Do Not Represent The Class Adequately.

In order to satisfy Rule 23(a)(4)'s adequacy requirement, the DPPs "must show first that the interests of the representative party will not conflict with the interests of any of the class members, and second, that counsel chosen by the representative party is qualified, experienced and able to vigorously conduct the proposed litigation."[91] Neither FWK nor RDC satisfies this test. FWK has a clear conflict of interest given the close business and personal relationship between its sole member and class counsel—a conflict that makes FWK unsuited to represent the interests of absent class members, as evidenced by its failure to meaningfully supervise this litigation.[92] RDC, in turn, is compromised by evidence of repeated dishonesty and unlawful conduct, directly undercutting RDC's credibility, and fundamentally undermining its adequacy here.

A. FWK Is Not An Adequate Representative For The Proposed Class.

Unlike other plaintiffs in the proposed class, FWK does not purchase pharmaceutical products—instead, it was formed to buy lawsuits for class counsel. [redacted]

[89] *In re Modafinil Antitrust Litig.*, 837 F.3d 238, 259 (3d Cir. 2016) (vacating class-certification order of a putative direct purchaser class pursuing an antitrust challenge to a patent-litigation settlement).

[90] Dr. Leitzinger [redacted] In doing so, he implicitly relies on the premise that the DPPs' ability to pass on costs to subsequent purchasers in the distribution channel is legally irrelevant—a rule derived from the Supreme Court's decisions in *Hanover Shoe, Inc. v. United Shoe Machinery Corp.*, 392 U.S. 481 (1968), and *Illinois Brick Co. v. Illinois*, 431 U.S. 720 (1977). The Supreme Court is considering the viability and scope of this rule in *Apple Inc. v. Pepper*, No. 17-204 (U.S.). If the Court overturns or materially limits the *Hanover Shoe/Illinois Brick* rule, Defendants reserve the right to oppose certification (or seek decertification) on the basis of the *Apple* decision.

[91] *Andrews v. Bechtel Power Corp.*, 780 F.2d 124, 130 (1st Cir. 1985).

[92] *See In re IMAX Sec. Litig.*, 272 F.R.D. 138, 155 (S.D.N.Y. 2010) ("A key element in the determination of whether a plaintiff's interests are antagonistic to those of other members of the class is the relationship between the class representative and class counsel.").

[redacted].[93] [redacted].[94] [redacted].[95] [redacted].[96] [redacted].[97] [redacted].[98] [redacted].[99] [redacted].[100] [redacted].[101] [redacted].[102], FWK has filed several

[93] Ex. 39 (FWK Tr. 21:2-8, 154:4-7).
[94] *Id.* 154:8-12, 63:21-64:11, 65:10-16, 65:24-66:3 (describing relationship).
[95] *Id.* 15:24-16:9, 17:17-20.
[96] *See* Ex. 40 (FWK_INTUNIV_0003993); Ex. 41 (FWK_INTUNIV_0003990); Ex. 42 (FWK_INTUNIV_0003975); Ex. 43 (FWK_INTUNIV_0003996). On January 23, 2019, Mr. Vanek and Mr. Germaine submitted a "Notice of Change of Firm Affiliation" indicating that they are now affiliated with the firm Sperling & Slater, P.C., effective January 1, 2019. ECF No. 222.
[97] Ex. 39 (FWK Tr. 19:24-20:12, 51:4-12, 69:7-16).
[98] Ex. 44 (FWK_INTUNIV_0003980) (emphasis added).
[99] *Id.*
[100] Ex. 39 (FWK Tr. 11:4-12).
[101] *Id.* 10:17-11:3, 11:17-20.
[102] *Id*. 14:7-15:3.

additional antitrust actions as a class representative and has always used Mr. Vanek as its counsel.[103]

1. The Close Business And Personal Relationship Between Class Counsel And FWK Creates A Conflict That Undermines FWK's Ability To Represent The Class.

Because class representatives serve as "fiduciaries" for absent class members and are "charged with monitoring the lawyers who prosecute the case," courts have recognized that "[t]here ought . . . to be a genuine arm's-length relationship between class counsel and the named plaintiffs."[104] Indeed, "[n]umerous courts" have "found that a named plaintiff is an inadequate representative where there is a close personal relationship between a plaintiff and class counsel" because such a relationship undermines confidence that the representative will protect the interests of ***the class***, as compared to the (potentially divergent) interests of counsel.[105] "[A] close relationship need not be familial in order to raise adequacy issues: 'a close . . . business relationship or friendship with class counsel' is enough."[106] Moreover, even a "***potential*** conflict of interest is sufficient to render a named plaintiff an inadequate class representative."[107]

Here, [redacted][108] [redacted]

[redacted]

[103] *Id.* 68:6-9.
[104] *Redman*, 768 F.3d at 638 (quotation marks and citation omitted).
[105] *Spagnola v. Chubb Corp.*, 264 F.R.D. 76, 96 (S.D.N.Y. 2010) (collecting decisions); *see also, e.g.*, *London v. Wal-Mart Stores, Inc.,* 340 F.3d 1246, 1255 (11th Cir. 2003) (reversing a grant of class certification where the proposed representative was a friend of, and previously served as the stockbroker for, class counsel); 5 *Moore's Federal Practice* – Civil § 23.25[2][b][vi] (3d ed. 2017) ("[I]f a class representative is closely affiliated with class counsel, courts usually consider this to be a disqualifying conflict of interest.").
[106] *In re LIBOR-Based Fin. Instruments Antitrust Litig.*, 299 F. Supp. 3d 430, 566 (S.D.N.Y. 2018) (quoting 1 *Newberg on Class Actions* § 3:70 (5th ed.)); *see also Susman v. Lincoln Am. Corp.,* 561 F.2d 86, 90 & n.7 (7th Cir. 1977) ("[A] majority of courts . . . have refused to permit class attorneys . . . or [their] *business associates* from acting as the class representative." (emphasis added)).
[107] *In re LIBOR*, 299 F. Supp. 3d at 565 (emphasis added; quotation marks omitted).
[108] *See* Ex. 39 (FWK Tr. 6:6-7) (Mr. Vanek noting his representation "on behalf of the Class").

[redacted][109] [redacted]

[redacted][110] [redacted]

[redacted]

[redacted].[111] [redacted]

[redacted]

[redacted].[112] By then, fact discovery in this matter was largely complete and the DPPs already had filed their certification motion.

Most notably, [redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted].[113] [redacted]

[redacted]

[redacted].[114]

Given these facts, there plainly is not a "genuine arm's-length relationship between class counsel" and FWK.[115] After all, [redacted], the resulting conflict of

[109] *Id.* 65:24-66:13.
[110] *Id.* 63:21-64:11.
[111] *Id*. 180:9-19; Ex. 45 (Decl. of Thomas L. Kolschowsky ("Kolschowsky Decl.") ¶¶ 7-8, 14-15).
[112] *See* Ex. 46 (Letter from David S. Nalven to Defense Counsel, Dec. 17, 2018); Ex. 47 (FWK_INTUNIV_ 0004003); Ex. 48 (FWK_INTUNIV_0003999); Ex. 49 (FWK_INTUNIV_0004001) ([redacted]); Ex. 45 (Kolschowsky Decl. ¶¶ 7-8, 14-15).
[113] *See* p. 17, *supra*.
[114] Ex. 39 (FWK Tr. 19:2-7); Ex. 50 (FWK_INTUNIV_0003985); *see also* note 95, *supra* ([redacted]).
[115] *Redman*, 768 F.3d at 638.

interest clearly would defeat certification.[116] The same basic conflict exists here, [redacted]. Moreover, it is no answer that Mr. Vanek and his firm are working with additional class counsel, or that counsel from Hagens Berman Sobol Shapiro LLP have experience litigating antitrust actions.[117] The conflict of interest is no less problematic merely because Vanek & Vickers (and now Sperling & Slater) has partnered with another firm to pursue the case, particularly since that other firm (Hagens Berman) [redacted][118] and FWK's [redacted][119]

2. FWK Lacks The Capacity And Incentive To Supervise The Litigation.

Class representatives also are inadequate if they "have so little knowledge of and involvement in the class action that they would be unable or unwilling to protect the interests of the class against the possibly competing interests of the attorneys."[120] Unsurprisingly, [redacted], FWK lacks both the experience and the incentive needed to supervise this litigation in any meaningful way.

To begin with, neither FWK nor its principals—*i.e.*, Mr. Stahelin and the company's putative manager and general counsel, Mr. Kolschowsky—[redacted].[121] [redacted]

[116] *See Susman*, 561 F.2d at 90 & n.7.
[117] *See* DPP Mem. 13.
[118] Ex. 51 (FWK_INTUNIV_0003983).
[119] Ex. 39 (FWK Tr. 169:10-13).
[120] *In re Monster Worldwide, Inc.*, 251 F.R.D. 132, 135 (S.D.N.Y. 2008) (quoting *Baffa v. Donaldson, Lufkin & Jenrette Sec. Corp.*, 222 F.3d 52, 61 (2d Cir. 2000)); *accord In re Sepracor Inc.*, 233 F.R.D. 52, 55 (D. Mass. 2005) (finding proposed class representative inadequate due to his "lack of basic knowledge about th[e] case").
[121] Ex. 39 (FWK Tr. 33:6-34:7, 248:20-24).

[redacted].[122] Moreover, [redacted].[123] [redacted].[124] [redacted][125] [redacted].[126]

In short, FWK does not have the ability to represent the proposed DPP class in a complex antitrust lawsuit, and it has shown no interest in trying. Rather, the company has simply "abdicated control of the litigation to class counsel."[127]

B. RDC Is Not An Adequate Representative For The Proposed Class.

RDC also is an inadequate class representative, but for a different reason: Recently, evidence has emerged of a culture of dishonesty at the company that raises serious "doubts about [its] ability to fulfill [its] fiduciary obligations as [a] class representative[]."[128] Courts have recognized that in order "[t]o judge the adequacy of representation," it is appropriate to "consider the honesty and trustworthiness of the named plaintiff."[129] Indeed, "it is self-evident that a Court must be concerned with the integrity of [parties] it designates as representatives for a large class

[122] *Id.* 87:17-88:15; Bell Report ¶ 50.
[123] Ex. 39 (FWK Tr. 10:17-23).
[124] *Id.* 36:5-16.
[125] *Id.* 89:23-91:10.
[126] *Id.* 204:9-205:19.
[127] *Maskowitz v. La Suisse, Societe D'Assurances sur la Vie*, 282 F.R.D. 54, 72 (S.D.N.Y. 2012) (denying class-certification motion where, among other things, the proposed class representatives lacked sufficient knowledge "to protect the interests of the class").
[128] 5 *Moore's Federal Practice - Civil* § 23.25[2][e] (3d ed. 2017) (collecting decisions in which past criminal conduct or a pattern of dishonesty was found to render a proposed class representative inadequate).
[129] *Gooch v. Life Investors Ins. Co. of Am.*, 672 F.3d 402, 431 (6th Cir. 2012) (quoting *Savino v. Computer Credit Inc.*, 164 F.3d 81, 87 (2d Cir. 1998)); *see also Friedman-Katz v. Lindt & Sprungli (USA) Inc.*, 270 F.R.D. 150, 160 (S.D.N.Y. 2010).

of plaintiffs."[130] As this Court put it in its order denying RDC's motion to block discovery into the active investigations involving RDC, participation in unlawful conduct "bears on a Plaintiff's adequacy under Rule 23, at least where [that] conduct is close in time to the events at issue and could lead reasonable minds to question whether a potential institutional class representative has a culture of dishonesty or disrespect for the law."[131]

As it turns out, RDC engaged in repeated and serious violations of federal law during a period of time that overlaps with the class period (October 2012 to June 2015). Since 2013, RDC has been subject to at least three Drug Enforcement Agency ("DEA") investigations prompted by RDC's failure to report drug sales as required by the Controlled Substances Act ("CSA").[132] RDC entered into a consent decree in 2015, in which the company paid a fine and admitted to violations of the CSA between July 2012 and July 2014.[133] [redacted].[134]

Notably, [redacted].[135] And while the

[130] *Del Campo v. Am. Corrective Counseling Servs., Inc.*, 2008 WL 2038047, at *4 (N.D. Cal. May 12, 2008).
[131] ECF No. 210, at 4.
[132] *See, e.g.*, Ex. 52 (RDC Tr. 66:18-67:24) ([redacted]), 70:7-20 ([redacted]).
[133] *See* Ex. 53 (RDC Dep. Ex. 5 (consent order), at 2).
[134] *See, e.g.,* Ex. 52 (RDC Tr. 73:14-75:6, 69:3-22 ([redacted]), 70:7-20 ([redacted])).
[135] Ex. 52 (RDC Tr. 60:10-25, 118:6-25, 62:9-15 ([redacted]).

DPPs [redacted][136] [redacted][137] Moreover, in ongoing civil litigation with RDC, Mr. Doud alleges that RDC's current CEO, Mr. Joseph Brennan—who served as RDC's Chief Operating Officer from 2013-2017—was the primary person responsible for RDC's violations and then conspired with others at RDC to shift the blame to Mr. Doud.[138] According to Mr. Doud, RDC itself accused him of being "involved in a 'kickback scheme'" with the owner of one of RDC's customers whereby Mr. Doud "was purportedly directly paid to falsely report" sales, having a "side deal'" with another entity that "was the true cause of the DOJ [investigations], and, that as a result, Mr. Doud "was going to prison for his role in [RDC's] recent violations of the CSA."[139]

Finally, the ongoing civil and criminal investigations are impacting RDC's ability to be an honest broker for a purported class. RDC advised the Court on November 7, 2018 as follows: [redacted][140] But at its December 11, 2018 deposition [redacted][141]

[136] Ex. 52 (RDC Tr. 138:18-144:13).
[137] *See id.*
[138] *See, e.g.*, *Doud v. Rochester Drug Co-Operative, Inc. et al.*, No. 6:18-cv-06557-FPG-JWF, ECF No. 25 ¶¶ 35, 42, 50, 53-66 (W.D.N.Y. July 12, 2018).
[139] *Id.* at ¶¶ 54-55.
[140] ECF No. 206, at 2.
[141] Ex. 52 (RDC Tr. 75:7-77:3).

Given RDC's admitted bad conduct during the class period and the existence of ongoing federal investigations that may bring still more examples of dishonesty and wrongdoing to light, RDC cannot serve as a reliable fiduciary for absent class members.[142]

II. The Claims Of The Two Proposed Representatives Are Not Typical Of The Class.

Rule 23(a)(3)'s "typicality" requirement is closely related to adequacy,[143] and the DPPs' motion unsurprisingly fails to satisfy this Rule 23 prong as well. "The primary focus of the typicality analysis is the functional 'question of whether the putative class representative can fairly and adequately pursue the interests of the absent class members without being sidetracked by her own particular concerns.'"[144] Here, for reasons discussed above, both FWK and RDC fail this test. As an artificial litigation entity created by and for class counsel, FWK is fundamentally dissimilar from the other class members. [redacted][145] [redacted], and thus it has very different litigation incentives than operating companies.[146] Likewise, RDC, [redacted], is subject to credibility challenges that do not apply to other class members.[147]

In addition to these problems, FWK and RDC also are not typical of the class as a whole because the class combines three materially different categories of purchasers without creating

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[142] This is not the first time that RDC's adequacy as a class representative has been challenged based on its "potential criminal exposure." *In re Loestrin 24 FE Antitrust Litig.*, No. 13-md-02472, ECF No. 657, at 10-11. (D.R.I. Dec. 14, 2018). In *In re Loestrin*, DPP counsel "repeatedly instructed RDC's 30(b)(6) witness . . . not to answer Defendants' questions relating to the criminal investigation." *Id*. at 2. DPP counsel then resorted to a "clumsy Hail Mary pass to another court" by filing a sealed action to terminate the RDC deposition. *Id*. at 3-4, 9. When that gambit failed, RDC elected to withdraw as a class representative rather than face further scrutiny.

[143] *See In re Credit Suisse-AOL Sec. Litig.*, 253 F.R.D. 17, 22-23 (D. Mass. 2008).

[144] *Shanley v. Cadle*, 277 F.R.D. 63, 69 (D. Mass. 2011) (quoting *Swack v. Credit Suisse First Boston*, 230 F.R.D. 250, 264 (D. Mass. 2005)).

[145] *See* Ex. 39 (FWK Tr. 86:12-20).

[146] *See Georgine v. Amchem Prods., Inc.*, 83 F.3d 610, 631-32 (3d Cir. 1996) (noting that typicality "assesses whether the named plaintiffs have incentives that align with those of absent class members" and ordering the district court to decertify class when, among other things, the court could not say that named plaintiffs' incentives were so aligned).

[147] *See Garcia v. E.J. Amusements of N.H., Inc.*, 98 F. Supp. 3d 277, 288 (D. Mass. 2015) ("Typicality may be defeated where the class representatives are subject to unique defenses which threaten to become the focus of the litigation.") (citations omitted).

subclasses. Specifically, the proposed class includes (1) [redacted] wholesalers and distributors (including the Big Three); (2) [redacted] self-warehousing retail pharmacies; (3) [redacted] PBMs with mail-order pharmacies; and (4) and [redacted] staff-model HMO.[148] As Dr. Bell explains, [redacted].[149] The two named representatives are wholesalers and distributors (FWK by virtue of its assignment), and "given the different economic interests" of the four DPP groups, FWK and RDC "will not serve as adequate and typical representatives" of absent plaintiffs in the other three.[150] Indeed, even within the general category of wholesalers and distributors, FWK and RDC are very differently situated than the Big Three, [redacted].[151] FWK and RDC thus are not adequate and typical representatives of those absent plaintiffs either.

III. Joinder Is Practicable Because The Proposed Class Is Not Sufficiently Numerous.

The DPPs also fail to show, under Rule 23(a)(1), that the proposed class "is so numerous that joinder of all members is impracticable." Although this Rule is often called the "numerosity requirement," the First Circuit has made clear that "numbers alone are not usually determinative."[152] Indeed, courts in this District have explained that Rule 23(a)(1) "might more

[148] Bell Report ¶¶ 12, 88.
[149] *See id.* ¶¶ 48-61, 64-65, 84-85.
[150] *In re Pharm. Indus. Average Wholesale Price Litig.*, 230 F.R.D. 61, 80 (D. Mass. 2005); *see also* Bell Report ¶¶ 84-85.
[151] *See, e.g.*, Bell Report ¶¶ 50-51(e).
[152] *Andrews*, 780 F.2d at 131-32 (affirming the denial of a class with 49 members based on the failure to satisfy Rule 23(a)(1)); *see also* 7A *Wright & Miller, Fed. Prac. & Proc. Civ.* § 1762 (3d ed. 2018) (collecting decisions holding that Rule 23(a)(1) had not been satisfied despite the proposed class including 50 or more members); 1 *Newberg on Class Actions* § 3:12 (5th ed. 2011) (same). The DPPs contend that Rule 23(a)(1) is generally satisfied if the proposed class includes more than 40 potential plaintiffs, but the only First Circuit decision they cite in support included "around 500,000" class members. *Garcia-Rubiera v. Calderon*, 570 F.3d 443, 460 (1st Cir. 2009).

properly be called the 'impracticability' requirement, because the inquiry called for by Rule 23(a)(1) often involves more than merely counting noses."[153]

In recent years, courts have increasingly scrutinized whether DPP class actions in pharmaceutical antitrust cases satisfy Rule 23(a)(1), and multiple courts have denied certification on this basis.[154] As the Third Circuit recognized in *Modafinil*, these cases differ markedly from "the typical class action" because just three absent class members—the "Big Three" wholesale purchasers—make up approximately 90% of the total class claims, which are substantial in magnitude.[155] Given this feature of the proposed class, and because the remaining class members also are sophisticated companies with significant damage claims, joinder is not impracticable and class certification is improper.

A. The DPPs Have Artificially Inflated The Number Of Class Members.

The DPPs identify forty-eight potential plaintiffs in their proposed class.[156] But the DPPs arrive at this number through impermissible double-counting and by grouping together plaintiffs who do not belong in the same class. To begin with, the DPPs count several corporate affiliates as distinct plaintiffs, even though it clearly would be practicable to join those affiliates together in the same suit. When affiliates are grouped together, as they should be,[157] [redacted]. [redacted].[158] In addition, the DPPs improperly inflate their class by [redacted]

[153] *DeRosa v. Mass. Bay Commuter Rail Co.*, 694 F. Supp. 2d 87, 97 (D. Mass. 2010) (quoting *McLaughlin v. Liberty Mut. Ins. Co.*, 224 F.R.D. 304, 307 (D. Mass. 2004)).

[154] *See, e.g., In re Modafinil*, 837 F.3d at 249-60 (vacating class certification and remanding for consideration of numerosity requirement); *King Drug Co. of Florence, Inc. v. Cephalon, Inc.*, 2017 WL 3705715 (E.D. Pa. Aug. 28, 2017) (holding on remand from *Modafinil* decision that the proposed class did not satisfy numerosity); *In re Androgel Antitrust Litig.*, 2018 WL 3424612 (N.D. Ga. July 16, 2018) (holding that a proposed DPP class could not establish numerosity).

[155] 837 F.3d at 258-59.

[156] DPP Mem. 10 & n.63; Ex. 1 to DPP Mem. ("Leitzinger Report") at Leitzinger's Ex. 5.

[157] See *In re Nexium (Esomeprazole) Antitrust Litig.*, 296 F.R.D. 47, 51 (D. Mass. 2013) (consolidating subsidiaries with their parents for numerosity analysis).

[158] *See* Bell Report ¶¶ 88.

[redacted],[159] and [redacted].[160] Those individuals should not be included in the DPP class either, since they must be excluded from any recovery.[161] [redacted].[162]

In addition, the DPPs should not be allowed to group dissimilar groups of plaintiffs in a single class in an effort to avoid numerosity objections.[163] As discussed, p. 24, *supra*, the proposed class includes at least four distinct groups of purchasers: wholesalers and distributors, self-warehousing retail pharmacies, PBMs with mail-order pharmacies, and [redacted]staff model HMO. These groups cannot be joined in a single class, because the plaintiffs in each group are not typical of the remaining plaintiffs in the other three.[164] [redacted].[165]

B. Joinder Is Practicable And Preferred To A Class Action In Which Three Plaintiffs Who Account For The Overwhelming Majority Of The Class Claims Sit On The Sidelines.

Even if all forty-eight proposed plaintiffs were counted as falling within a single class, the DPPs still could not satisfy Rule 23(a)(1) because joinder is entirely practicable. In evaluating the practicability of joinder, courts consider the financial resources of the class members, the claimants' ability and interest to bring suits as joined parties, judicial economy,

[159] *Id.* ¶ 71, Bell Ex. G.
[160] *Id.* ¶ 71, Bell Ex. I.
[161] *See In re Nexium Antitrust Litig.*, 777 F.3d 9, 31-32 & n.28 (1st Cir. 2015).
[162] *See* Bell Report ¶¶ 71(a)-(b).
[163] *See Andrews*, 780 F.2d at 129-30 (evaluating numerosity based on the class as it was limited by the district court, because the class as initially proposed without subclasses could not satisfy other 23(a) requirements).
[164] *See* pp. 24-25, *supra*.
[165] Bell Report ¶ 88.

geographic dispersion, and the form of relief.[166] Considered in their totality, these factors push decisively against class certification here.

Most significantly, the absent class members plainly have the ability and financial interest to participate in this litigation as joined parties, and they can do so without compromising judicial efficiency. As discussed, the "Big Three" wholesalers account for 89.3% of the total purchases at issue in this case, and thus "can hardly be considered candidates who need the aggregate advantages of the class device."[167] Even beyond the "Big Three," the DPPs have made no effort to meet their burden to show that "it would be uneconomical" for the remaining parties "to be individually joined as parties in a traditional lawsuit."[168] Nor could they because, "[a]s joined parties, no individual plaintiff [would] bear" litigation costs on its own, since the class plaintiffs "would very likely sign joint litigation agreements and hire joint experts."[169] Actual experience shows this is feasible. For example, in the *Modafinil* litigation, after the district court refused to certify a direct purchaser class for lack of numerosity on remand, 22 of the 25 class members participated in the litigation as joined parties.[170]

Other factors also support requiring the use of joinder rather than class certification here. The class is seeking damages (not injunctive relief),[171] and its members are both easily identifiable and amenable to service because the DPPs "already know each and every one of the

[166] *In re Modafinil*, 837 F.3d at 250, 253.
[167] *Id.* at 258.
[168] *Id.* at 259.
[169] *In re Androgel*, 2018 WL 3424612, at *3; *accord King Drug*, 2017 WL 3705715, at *7-8 (explaining that "cost and resource sharing mechanisms exist" to address concerns about judicial economy in the context of a "small" proposed class, and noting that it is common for plaintiffs to use "jointly retained experts" and to file joint pleadings).
[170] *See King Drug*, No. 2:06-cv-1797, ECF No. 1195 (E.D. Pa. Dec. 3, 2018) (settlement of 21 plaintiffs following *Modafinil* remand); *United Healthcare Servs., Inc. v. Cephalon, Inc.*, No. 2:17-cv-555 (E.D. Pa.) (docket reflecting ongoing litigation by plaintiff United Healthcare in case related to *King Drug* following *Modafinil* remand).
[171] *See King Drug*, 2017 WL 3705715, at *11 ("As Direct Purchasers are not seeking injunctive relief, this [factor] weighs against certification of the Direct Purchaser class.").

potential plaintiffs."[172] And though the DPPs assert that the plaintiffs' "geographic dispersion" supports class certification, the nature of the proposed class—which "consists of very large, sophisticated companies with very large claims"[173]—"undercut[s] the weight that should be placed on this factor."[174]

IV. The DPPs Have Not Shown Common Issues Predominate Over Individual Ones.

Rule 23(b)(3)'s predominance requirement "is even more demanding than Rule 23(a)."[175] The DPPs also fail to satisfy this requirement. As they acknowledge, to establish predominance, the DPPs must "show that antitrust impact is capable of proof at trial through evidence that is common to the class rather than individual members."[176] In addition, they also must show that their proposed damages methodology "reflect[s] the[ir] liability theory."[177] The DPPs' motion fails on both counts.

As explained in Dr. Bell's report, [redacted].[178] But the report of the DPP's expert, Dr. Leitzinger, [redacted].[179] By

[172] *In re Androgel*, 2018 WL 3424612, at *2.
[173] *Id*.
[174] *King Drug*, 2017 WL 3705715, at *11.
[175] *Comcast Corp. v. Behrend*, 569 U.S. 27, 34 (2013).
[176] DPP Mem. 14 (quoting *In re Nexium Antitrust Litig.*, 777 F.3d 9, 24 n.20 (1st Cir. 2015)); *see also In re Rail Freight Fuel Surcharge Antitrust Litig.*, 725 F.3d 244, 253 (D.C. Cir. 2013) (expert's models "are essential to the plaintiffs' claim they can offer common evidence of classwide injury. No damages model, no predominance, no class certification" (citation omitted)).
[177] *In re Nexium*, 777 F.3d at 23; *see Comcast*, 569 U.S. at 35.
[178] *See, e.g.* Bell Report ¶¶ 62-65.
[179] *See id.* ¶¶ 66, 71.

proceeding in this way, [redacted].[180] [redacted].[181] Likewise Dr. Bell [redacted].[182] [redacted]

In addition to those general problems, Dr. Leitzinger's methodology [redacted]. As explained, pp. 11-12, *supra*, the DPPs' allegation that Shire agreed not to launch an AG during Actavis's first 180 days on the market is [redacted].[183] Apparently recognizing this problem, the DPPs have tried to hedge their bets by relying on the novel legal theory that the Shire-Actavis licensing agreement would "still unlawfully restrict[] competition" ***regardless*** of whether it was a "No-AG" agreement; according to the DPPs, the agreement would be unlawful even if it merely restricted Shire's ability to grant multiple licenses to third-parties.[184]

Significantly, Dr. Leitzinger's report [redacted]

[180] *Id.* ¶ 71.
[181] *Id.* ¶¶ 64, 71(a).
[182] *Id.* ¶ 9, 71(b), Bell Ex. I.
[183] Ex. 24 (Actavis-Int-0000001, at -023, Section 2.3) ("[redacted]").
[184] DPP Mem. 8.

[redacted].[185] To the contrary, Dr. Leitzinger's report [redacted] [redacted][186] thus revealing that his methodology [redacted]. Under the DPPs' alternative theory, however, [redacted], because the theory recognizes that the decision not to launch could have been the result of Shire's unilateral action rather than an unlawful agreement; under that scenario, any price differences allegedly attributable to Shire's decision not to launch an AG could ***not*** be included in an overcharge calculation.[187] Dr. Leitzinger's methodology [redacted].[188]

The Supreme Court's *Comcast* decision makes clear that Dr. Leitzinger's [redacted] is fatal to their certification motion. As the Court explained, "at the class-certification stage (as at trial), any model supporting a plaintiff's damages case must be consistent with its liability case, particularly with respect to the alleged anticompetitive effect of the violation."[189] Dr. Leitzinger's model fails this test, [redacted].[190] The Court should accordingly deny their motion for class certification.[191]

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[185] Bell Report ¶ 75.
[186] Leitzinger Report ¶ 42 n.68 & Ex. 7.
[187] *See Comcast,* 569 U.S. at 38 ("Prices whose level above what an expert deems 'competitive' has been caused by factors unrelated to an accepted theory of antitrust harm are not 'anticompetitive' in any sense relevant here.").
[188] *See* Bell Report ¶ 75.
[189] *Comcast*, 569 U.S. at 35 (quotation marks omitted).
[190] *Id*.
[191] *See In re Celexa & Lexapro Mktg. & Sales Practices Litig.*, 315 F.R.D. 116, 129 (D. Mass. 2016) (denying motion for class certification in antitrust case where the plaintiffs' expert report "lacks both an accepted theory of liability and a valid model of damages").

V. A Class Action Is Not Superior To Joinder Under Rule 23(b)(3).

Finally, the proposed DPP class also should not be certified under Rule 23(b)(3) because a class action is not "superior" to individual representation and joinder. "[I]n large claim situations, courts generally find individual suits superior to a class action."[192] Rule 23 "was not designed to permit large claimants, who are fully capable of proceeding on their own, to strengthen their bargaining position by threatening their adversaries with the prospect of class-wide relief and large attorney fee awards."[193] Here, a class action would not be appropriate given the small size of the proposed class, the magnitude of the asserted claims, and the conspicuous absence of the three plaintiffs who have by far the most at stake in this action.

CONCLUSION

The Court should deny the DPPs' motion to certify a class action.

[192] 2 *Newberg on Class Actions* § 4:88 (5th ed. 2012); *accord* 5 *Moore's Fed. Prac. Civil* § 23.46[2][b][i] (3d ed. 2017) ("Frequently, the presence of large individual damage claims has been viewed as supporting an interest of the class members in separate litigation."); *see also, e.g.*, *Newton v. Merrill Lynch, Pierce, Fenner & Smith, Inc.*, 259 F.3d 154, 191 (3d Cir. 2001) (holding that the proposed class failed the superiority requirement where "some class members, such as large institutional investors who fall within the class definition, arguably would have a significant financial stake to raise stand-alone claims").

[193] *Stoudt v. E.F. Hutton & Co., Inc.*, 121 F.R.D. 36, 38 (S.D.N.Y. 1988).

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Respectfully submitted,

/s/ Joshua S. Barlow
Fred A. Kelly, Jr., Esq., BBO #544046
Joshua S. Barlow, Esq., BBO #667472
HAUG PARTNERS LLP
1 Post Office Square
Boston, MA 02109
Tel: (617) 426-6800
fkelly@haugpartners.com
jbarlow@haugpartners.com

Michael F. Brockmeyer, Esq., (*pro hac vice*)
David S. Shotlander, Esq., (*pro hac vice*)
Amanda J. Hamilton, Esq., (*pro hac vice*)
HAUG PARTNERS LLP
1667 K Street, NW
Washington, DC 20006
Tel: (202) 292-1530
Fax: (202) 292-1531
mbrockmeyer@haugpartners.com
dshotlander@haugpartners.com
ahamilton@haugpartners.com

Attorneys for Shire LLC and Shire US, Inc.

/s/ Christopher T. Holding
Christopher T. Holding (BBO# 600627)
Sarah K. Frederick (BBO# 679885)
Srikanth Reddy (BBO# 669264)
Alicia Rubio-Spring (BBO# 692640)
GOODWIN PROCTER LLP
100 Northern Avenue
Boston, Massachusetts 02210
T: 617 570-1000
F: 617 523-1231
CHolding@goodwinlaw.com
SFrederick@goodwinlaw.com
SReddy@goodwinlaw.com
ARubio-Spring@goodwinlaw.com

Attorneys for Actavis Elizabeth LLC and Actavis Holdco U.S., Inc.

CERTIFICATE OF SERVICE

I hereby certify that the foregoing redacted document was sent electronically to counsel of record on February 27, 2019.

/s/ Christopher T. Holding